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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/002,251   | 10/26/2001  | Raymond F. Cracauer  | FORS-06479          | 3020             |
| 7590   | 10/03/2003  |                      | EXAMINER            |                  |
| MEDLEN & CARROLL, LLP<br>Suite 350<br>101 Howard Street<br>San Francisco, CA 94105 |             |                      | SHEINBERG, MONIKA B |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1634                |                  |

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                |                      |  |
|------------------------------|--------------------------------|----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>         | <b>Applicant(s)</b>  |  |
|                              | 10/002,251                     | CRACAUER, RAYMOND F. |  |
|                              | Examiner<br>Monika B Sheinberg | Art Unit<br>1634     |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_\_.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) 12-21 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-11 and 22-38 is/are rejected.

7) Claim(s) 8 is/are objected to.

8) Claim(s) 1-38 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 10/26/2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: *Detailed Action* .

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## DETAILED ACTION

### Election/Restrictions:

The instant application requires two species election requirements with respect to the pending claims 1-38. Please note that a combination option is available [see (h) and (o)]. This entails that a specific combination of elements to the energy or heating components must be specified by the applicant as the required limitations for the instant invention; for example: a heating coil, an oscillating member and a constant energy input. Applicant is reminded that two elections of the invention to be examined are required for a response to the instant action to be complete even though the requirement may be traversed.

### 1<sup>st</sup> of 2 Species Election Requirements

This application contains claims directed to the following patentably distinct species of the claimed invention with respects to the energy component:

|   |   |
|---|---|
| a) Heating coil (claim 11),                           | e) Oscillating member (claim 15),                                   |
| b) Heat blanket (claim 12),                           | f) Periodic energy input (claim 16),                                |
| c) Heated room (claim 13),                            | g) Constant energy input (claim 17),                                |
| d) Energy in the electromagnetic spectrum (claim 14), | h) Or a <i>specific</i> combination of the above (i.e: a, e and g). |

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Furthermore, if Applicant elects species (h), Applicant is required to elect a specific combination to be examined. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**2<sup>nd</sup> Species Election Requirement**

This application contains claims directed to the following patentably distinct species of the claimed invention with respects to the heating component:

|  |   |
|--|---|
| i) Resistance heater (claim 18),         | m) Heated fluid (claim 22),                           |
| j) Peltier device (claim 19),            | n) Heated gas (claim 22),                             |
| k) Magnetic induction device (claim 20), | o) Or a specific combination of the above (i.e: j and |
| l) Microwave device (claim 21),          | n).   |

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Furthermore, if Applicant elects species (o), Applicant is required to elect a specific combination to be examined. Currently, claims 1 and 7 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**Election**

During a telephone conversation with David Casimir on September 26, 2003 a provisional election was made to prosecute the invention of claims 1-38, with respect to a species election of a heating coil (claim 11) for the energy component and a heated fluid (claim 22) for the heating component. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

- Claims 1-11 and 22-38 are hereby examined.

**Provisional Double Patenting**

Claims 1-10, 23-28 and 31-38 of this application conflict with claims 1, 18, 21-23, 25, 26, 32, 33, 44, 45, 48, 49, 52, 54, 56-58, 63, 64, 68, 69, 73-75, 77-79, 81-87, 91, 92, 94 and 95 of Application No. 09/930,535. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claims 1-11, 22-35 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 38 are vague and indefinite due to the lack of clarity of the term “imparts” line 2. The metes and bounds of the parameters that describe the term “imparts” are unclear. As such, claims 2-11 and 22-35 are also indefinite due dependency from claim 1.

Claim 2 is vague and indefinite due to the lack of clarity of the term “fail-safe” line 1. The metes and bounds of the parameters that describe the term “fail-safe” are unclear. As such, claims 3-6 are also indefinite due dependency from claim 2.

Claim 5 is vague and indefinite due to the lack of clarity of the term “large” line 2. The metes and bounds of the parameters that describe the term “large” are unclear. As such, claim 6 are also indefinite due dependency from claim 5.

Claim 10 is vague and indefinite as to what is meant by the limitation “from about 20 to about 60 degrees Celsius”. Clarification of the metes and bounds of the claim is requested; whether the temperature is 0°-100°C or is it 19°-50°C, etc.

Claim 34 is vague and indefinite as to what is meant by the limitation “room” lines 1 and 2. The metes and bounds of the parameters that describe the term “room” are unclear; for example if an actual physical room of a building or merely a chamber of the apparatus.

#### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- Claims 1, 2, 7-11, 22, 23, 25, 36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Mullis et al. (US Patent 5,656,493; 12-Aug-1997).

Regarding claims 1, 7, 8 and 38, Mullis et al. teaches an apparatus for continuous nucleic acid synthesis (column 2, lines 51-60) wherein the thermal energy, thereby a heating component,

is provided to the reaction wells (containing tubes) for temperatures specific for nucleic acid synthesis (column 16, lines 62-67).

Regarding claims 2 and 9, Mullis et al. teaches a reagent delivery system in which the fluid reservoirs are heated or cooled can be (Figure 8, labeled 67A, 58A, and 68A), thereby capable of providing heated solutions to the reaction.

Regarding claim 10, Mullis et al. teaches the capable range of temperatures to be “about 30-35 to 105 C” (column 14, lines 20-23).

Regarding claim 11, Mullis et al. teaches the use of a heating coil (column 2, lines 54-56).

Regarding claim 22, Mullis et al. teaches heated fluids (column 3, lines 10-14; and column 5, lines 36-39).

Regarding claims 23 and 36, the mixing component (Figure 12 B) is taught by the flow chart demonstrating the ability for the reaction to be mixed a specified number of times (steps 224A to 226A).

Regarding claim 25, Mullis et al. teaches a reaction support to be a plate for the reaction wells (column 16, lines 52-57) wherein more than three reaction wells are available (Figure 10).

- Claims 1, 2, 7-9, 11, 22-25 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Feygin et al. (WO 98/57181; 17-Dec-1998).

Regarding claims 1, 8 and 38, Feygin et al. teaches a device that “provides for the effective individual heating of reaction vessels”, or columns, thereby providing an energy component for the increased yield in compound synthesis (page 4, lines 11-18).

Regarding claims 2 and 25, Feygin et al. teaches a reaction vessel supports with secure reagent delivery component, which “include pressure sealed injection and evacuation ports for each supported reaction vessel” (page 4, lines 23-26); as seen by Figure 4, there are more than three reaction vessels (labeled 10).

Regarding claims 7 and 11, Feygin et al. teaches each reaction vessel to be connected to a “simple resistive heating coil” (page 13, lines 17-22), thus teaching the heating component to be a heat coil.

Regarding claims 9 and 22, Feygin et al. teaches the ability to control temperature of the fluid reactants in a plurality of reaction vessels (page 15, lines 12-16).

Regarding claim 12, Feygin et al. teaches the heating component containing a blanket that is used to heat reactants contained with the vessels (page 12, lines 25-29).

Regarding claims 23, 24, 36 and 37, Feygin et al. teaches a mixing component as magnetic stirrer to mix reagents in the reaction vessels (page 13 line 35- page 14 line 20).

### **Claim Objections**

Claim 8 is objected to due to improper dependency from itself. Correction is required.

### **Drawing Objections**

Figures 1, 2, 4 and 5 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated (see Figures 1, 2, 4 and 5 of McLuen et al.; WO 99/65602; 23-Dec-1999). See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### **Conclusion**

- Claims 1-10, 23-28 and 31-38 are in conflict with Application No. 09/930,535 - Provisional Double Patenting.
- Claims 1-11, 22-35 and 38 are rejected under 35 U.S.C. 112, second paragraph.
- Claims 1, 2, 7-11, 22, 23, 25, 36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Mullis et al.
- Claims 1, 2, 7-9, 11, 22-25 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Feygin et al.
- Claim 8 is objected to for improper dependency.
- Drawing Objections.

No claim is allowed.

**Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Jehanne Souaya, can be reached at 703-308-6565. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

October 1, 2003  
Monika B. Sheinberg  
Art Unit 1634

*MBS*

JEHANNE SOUAYA  
PATENT EXAMINER  
Primary  
*Jehanne Souaya*  
10/1/03